

Remarks

Reconsideration of this Application is respectfully requested.

Upon entry of the foregoing amendment, claims 1-6 and 16 are pending in this application.

Support for the word "purified" in claim 16 is found, *inter alia*, in Figures 25-30, Figures 37-38, in the examples that describe those figures, and on page 26. Also, claim 16 has been rewritten in independent form.

No new matter is added by amendment. Therefore, entry of the amendments is believed proper and is respectfully requested. Applicants reserve the right to file one or more continuation applications directed to the canceled embodiments.

Miscellaneous

(1) The Terminal Disclaimer

Filed herewith is a terminal disclaimer over U.S. 5,595,898.

(2) The Supplemental Application Data Sheet

Filed herewith is a Supplemental Application Data Sheet in which the benefit claim is adjusted to cancel the benefit claim to PCT Application No. PCT/US86/02269, filed October 27, 1986 (abandoned) and to U.S. Application No. 06/793,980, filed November 1, 1985 (abandoned). The "Cross-Reference to Related Applications" paragraph in the specification has also been amended accordingly.

(2) The Sequence Requirements

On Office Action page 3, paragraph no. 7, the Examiner states that Applicants do not comply with the sequence requirements of 37 C.F.R. §§ 1.821-1.825. Applicants respectfully traverse this rejection.

The requirements for patent applications containing nucleotide sequence and/or amino acid sequence disclosures went into effect October 1, 1990, after the July 24, 1987, filing date of the earliest application to which the instant application claims benefit.

The *Federal Register*, Vol. 55, No. 84, page 18230, referring to the sequence listing rules, states that "the final rules will not apply, except on a voluntary basis, to continuation or divisional applications filed after the effective date unless any application upon which 35 U.S.C. § 120 priority is claimed was also subject to these rules." Accordingly, this application is not required to comply with 37 C.F.R. §§ 1.821-1.825 and this objection may be withdrawn.

In view of the foregoing, it is respectfully submitted that the instant application complies with the requirements for patent applications containing nucleotide sequence and/or amino acid sequence disclosure. Accordingly, reconsideration is respectfully requested.

The Objections to the Claims

At Office Action page 4, paragraph no. 8, claim 16 is objected to as depending from non-elected claims 7 and 10. Applicants respectfully traverse this objection.

Applicants have amended claim 16 to rewrite it in independent form.

Accordingly, this objection may be withdrawn.

The Rejections

1. The rejection under 35 U.S.C. § 101

At Office Action page 4, claim 16 is rejected under 35 U.S.C. § 101, as being directed to non-statutory subject matter. Applicants respectfully traverse this rejection. Applicants have amended claim 16 to refer to a purified polynucleotide molecule. Accordingly, this rejection may be withdrawn.

2. The rejection under 35 U.S.C. § 112, second paragraph

(a) "chimeric"

At Office Action page 5, paragraph 12, claim 2 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for reciting "chimeric." Applicants respectfully traverse this rejection.

Claim 2 is not indefinite because of its use of the word "chimeric." There is no evidence on the record that establishes that the artisan could not determine the metes and bounds of the claim as written, based on the explanation of "chimeric immunoglobulin" that is in the specification, for example, at page 48 as noted by the Examiner. Therefore, prima facie indefiniteness is not established and this rejection may be withdrawn.

(b) "said heavy chain or heavy chain fragment and light chain encoding units"

Claim 4-6 are rejected under 35 U.S.C. § 112, second paragraph for use of the phrase "said heavy chain or heavy chain fragment and light chain encoding units" in claim 4. The Examiner questions whether these units refer to the "dicistronic transcription unit" of claim 1.

Applicants have amended claim 4 to clarify that the heavy chain or heavy chain fragment and said light chain are separately operably linked to a sequence coding for a polypeptide secretion signal. Accordingly, this rejection may be withdrawn.

(c) "linked"

Claim 16 is said to be indefinite for reciting "linked" (in the independent claims from which it depends). The Examiner states that it is not clear in what manner the linkage occurs. Applicants respectfully traverse this rejection.

Claim 16 is not indefinite for not specifying the manner in which the linkage occurs. ." There is no evidence on the record that establishes that the artisan could not determine the metes and bounds of the claim as written. Therefore, *prima facie* indefiniteness is not established and this rejection may be withdrawn.

(d) Summary of the rejections under 35 U.S.C. § 112, second paragraph

Applicants respectfully assert that each and every one of the rejections under 35 U.S.C. § 112, second paragraph for enablement have been obviated by the amendments and remarks above. Accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

3. *The rejection under 35 U.S.C. § 112, first paragraph for enablement*

At Office Action page 7, paragraph 14, claims 1-6 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. Applicants respectfully traverse this rejection.

The Examiner states that the claims do not require that the encoded antibody bind antigen. Applicants respectfully assert that the claims are enabled as written and that the enablement standard does not require that the claims recite that the encoded antibody bind antigen.

4. *Summary of the rejections under 35 U.S.C. § 112, first paragraph for enablement*

Applicants respectfully assert that each and every one of the rejections under 35 U.S.C. § 112, first paragraph for enablement have been obviated by the amendments and remarks above. Accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

5. *Priority*

At Office Action page 10, paragraph 15, the Examiner states that the effective filing date of the instant application is deemed to be the filing date of U. S. Application No. 07/501,092 (March 29, 1990). Applicants respectfully traverse this rejection.

Applicants submit herewith a copy of U.S. Application No. 07/077,528, filed July 24, 1987 and also U.S. Application No. 07/142,039, filed January 11, 1988.

The Examiner states that 06/793,980 and 07/077,528 do not share copendency. Applicants respectfully traverse this. The relationship of the applications is as follows: 07/077,528 is a continuation-in-part of PCT/US86/02269 (which designated the United States), which was a continuation-in-part of 06/793,980. There was copendency in this series of cases.

6. *Summary of the benefit questions*

Applicants respectfully assert that each and every one of the questions regarding the benefit claim of the instant application have been obviated by the amendments and remarks above. Accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

7. *The rejections under 35 U.S.C. § 102*

Claim 16 is rejected under 35 U.S.C. § 102(b) over a series of articles, and under 35 U.S.C. 102(e) over Cabilly et al, US 4,816,567. Applicants respectfully traverse these rejections.

Wood does not anticipate the invention. Wood does not describe a polynucleotide molecule according to claim 16.

Sharon does not anticipate the invention. Sharon does not describe a polynucleotide molecule according to claim 16.

Ochi does not anticipate the invention. Ochi does not describe a polynucleotide molecule according to claim 16.

Morrison does not anticipate the invention. Morrison does not describe a polynucleotide molecule according to claim 16.

Boulianne does not anticipate the invention. Boulianne does not describe a polynucleotide molecule according to claim 16.

Cabilly/PNAS does not anticipate the invention. Cabilly/PNAS does not describe a polynucleotide molecule according to claim 16.

Early does not anticipate the invention. Early does not describe a polynucleotide molecule according to claim 16.

Zemel-Dreasen does not anticipate the invention. Zemel-Dreason does not describe a polynucleotide molecule according to claim 16.

Gillies does not anticipate the invention. Gillies does not describe a polynucleotide molecule according to claim 16.

Skerra is not art against the invention. Skerra was published in 1988, after Applicants' asserted benefit date of July 24, 1987.

Better is not art against the invention. Better was published in 1988, after Applicants' asserted benefit date of July 24, 1987.

Cabilly/'567 does not anticipate the invention. Cabilly/'567 does not describe a polynucleotide molecule according to claim 16.

8. *Summary of the rejections under 35 U.S.C. § 102*

Applicants respectfully assert that each and every one of the rejections under 35 U.S.C. § 102(b) and (e) have been obviated by the amendments and remarks above. Accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

9. *The rejection for obviousness type double patenting*

At page 15, paragraph 24, of the Office Action, claims 1-6 and 16 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2 and 4 of US 5,595,898. Applicants respectfully traverse this rejection.

However, to advance prosecution, submitted herewith is a terminal disclaimer.

Conclusion

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the examiner reconsider all presently outstanding objections and rejections and that they be withdrawn.

Applicants believe that a full and complete reply has been made to the outstanding office action and, as such, the present application is in condition for allowance. If the examiner believes, for any reason, that personal communication will

expedite prosecution of this application, the examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this supplemental amendment and reply is respectfully requested.

Respectfully submitted,

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Date: May 24, 2005

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Attachment A: A copy of U.S. Appln. No. 07/077,528, filed July 24, 1987.
Attachment B: A copy of U.S. Appln. No. 07/142,039, filed January 11, 1988.